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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,838

02/02/2005

Daniel W. Chan

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08/09/2007

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

08/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/500,838

Applicant(s)

CHAN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-5, 9-12, 34, 39, 40, 46, 47, 62, 63, 65, 70 and 81-84 is/are pending in the application.
- 4a) Of the above claim(s) 40, 46, 47, 63, 65, 70 and 81-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-5, 9-12, 34, 39 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/06/04; 09/07/04</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I (claims 3-5, 9-12, 34, 39 and 62) in the reply filed on July 9, 2007 is acknowledged. The traversal is on the ground(s) that Group I can be examined with Group V (claims 81-84). This is not found persuasive because as noted in the Election/Restrictions Requirement mailed May 15, 2007 there was no special technical feature recited that was a contribution over the prior art, hence the Groups I-V are not linked.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3-5, 9-12, 34, 39, 40, 46, 47, 62, 63, 65, 70 and 81-84 are pending.

Claims 40, 46, 47, 63, 65, 70 and 81-84, drawn to non-elected inventions are withdrawn from examination.

Claims 3-5, 9, 10, 39, 62, 65 and 70 have been amended.

Claims 81-84 have been added.

Claims 1, 2, 6-8, 13-33, 35-38, 41-45, 48-61, 64, 66-69 and 71-80 have been cancelled.

Claims 3-5, 9-12, 34, 39 and 62 are examined on the merits.

***Claim Objections***

3. Claim 3 is objected to because of the following informality: it cites "...at least one protein biomarkers...", which is not grammatically correct. Applicants should amend the claim to recite "...at least one protein biomarker...". Correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-5, 9, 10-12, 34, 39 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The claimed method recited in claim 3 reads on detecting and diagnosing ovarian cancer comprising measuring at least one protein biomarker, however the method only cites two steps and appears to lack complete steps. These two steps are measuring and correlating the measurement of one or more protein markers with a diagnosis of ovarian cancer. The claims are remiss of the reagents or components needed for quantitating or measuring and a conclusion step setting forth results of preamble or purpose of the claim. And while all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced. The method steps should at least include reagents necessary for the assay, a detection step in which the reaction

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products are quantitated or visualized and a correlation step describing how the presence of a biomarker equates to a positive diagnosis of ovarian cancer.

b. Claims 9, 10 and 11 are indefinite in the recitation "known biomarker". It is not clear if the markers set forth as Marker I-Marker VII have already been established as ovarian cancer markers and what the recitation means. Accordingly, the metes and bounds cannot be determined.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 3-5, 9-12, 39 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004). The patent discloses a method of determining of ovarian carcinoma in patients with the detection of CA 215, which has a molecular weight of 60 kd, see column 4, lines 11-21; Example 3 in column 13. Table 1 discloses serum levels of CA215 in healthy patients, as well as in patients with ovarian carcinoma by stages, see columns 14 and 15; column 15, lines 33-50; and column 16, lines 30-35.

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The CA 215 biomarker was assayed with known ovarian marker, CA 125, see Figures 6 and 10 and corresponding descriptions in column 3, lines 28-30, 49 and 50; and column 14, lines 1-13.

8. Claims 3-5, 9-12, 39 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004). The patent discloses a method of determining of ovarian carcinoma in patients with the detection of CA 215, which has a molecular weight of 60 kd, see column 4, lines 11-21; Example 3 in column 13. Table 1 discloses serum levels of CA215 in healthy patients, as well as in patients with ovarian carcinoma by stages, see columns 14 and 15; column 15, lines 33-50; and column 16, lines 30-35. The CA 125 biomarker was assayed with known ovarian marker, CA 125, see Figures 6 and 10 and corresponding descriptions in column 3, lines 28-30, 49 and 50; and column 14, lines 1-13.

9. Claims 3-5, 9-11, 39 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001). The patent application publication discloses methods of detecting, characterizing and staging ovarian cancers comprising correlating changes in the levels of expression of marker genes with the presence of ovarian cancer, see abstract. The disclosed "...methods may be performed by assessing the expression of a plurality of ...of ovarian cancer marker genes.", see page 2, section 0015; page 3,

section 0023; and page 9, sections 0135 and 0136. The markers for detection and diagnosis of ovarian cancer are listed in Table 1 beginning on page 35. Markers O49 (34 kD) and O82 (55 kD) are biomarkers that have molecular weights synonymous with Applicants' markers, Marker IV (of about 39.8 kD) and Marker V (of about 54 kD), respectively, see page 36. Marker O316 (58kD) is a biomarker that has a molecular weight of about 54 kD and 60 kD, which corresponds to Markers V and VI, respectively, see page 39. Markers O426 (52 kD) and O452 (36kD) are protein biomarkers having a molecular weight of about Marker V (54 kD) and Marker IV (39.8 kD), respectively, see page 40. The publication's markers O504 (58 kD), O512 (40 kD) and O517 (72 kD) are within the range of Applicants' Markers V, IV and VII, respectively, see page 41. A variety of formats can be employed to determine whether a sample contains a biomarker, see page 29 - page 32.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 3-5, 9-12, 34, 39 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent Application Publication number 2003/0003479 A1 (effective filing date April 19, 2001), and further in view of U. S. Patent Application Publication number 2003/0137106 A1 (effective filing date March 9, 2001) and U.S.

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Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004). The teachings of publication number 2003/0003479 are of record in the preceding 102(e) rejection. Publication '3479 does not teach a method of detection and diagnosis of ovarian cancer markers using laser desorption/ionization mass spectrometry and detecting CA 125.

However, Publication number 2003/0137106 teaches analyzing components of a biological pathway, such as the cell cycle that contributes to the development of cancers (i.e. breast and ovarian), see abstract; and page 4, section 0047. A biological sample can be assayed to detect components. The Examiner regards the prior art's components as reading on Applicants' markers. The components or markers are defective and contribute to a disease condition such as cancer with mass spectrometry including laser desorption/ionization, see page 8, sections 0089 and 0093. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was to made to implement the teachings of publication '7106 in a method of detecting and diagnosing ovarian cancer. One of ordinary skill in the art would have been motivated to implement this assay in the method of publication '3479 because the components or target markers can easily be captured by reagents on a substrate surface desorbed, ionized and detected to identify the present or absence of pathway components of specific mass to charge ratio, see publication '7106, page 6, sections 0098-0102.

Moreover, U.S. Patent 5,650,291 (issued July 22, 1997/ IDS reference AC submitted September 7, 2004) teaches an was assay comprising detecting protein

biomarkers with known ovarian marker, CA 125, see Figures 6 and 10 and corresponding descriptions in column 3, lines 28-30, 49 and 50; and column 14, lines 1-13. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was to make to implement the teachings of patent '291 in a method of detecting and diagnosing ovarian cancer. One of ordinary skill in the art would have been motivated to implement this assay in the method of the patent that ovarian markers can clearly be identified, distinguished and easily assayed, see entire patent.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

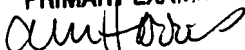
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER



Alana M. Harris, Ph.D.

01 August 2007